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EXAMINER

SODERQUIST, ARLEN

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/698,329	Applicant(s) Moon et al.	
	Examiner Arlen Soderquist	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 2, 2002

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 10 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

1. The amendment filed December 2, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the change in the specification changing monolithic chip to microchip is not supported by the specification because a microchip can have components which are made from a monolithic chip. Using the definition of a monocrystalline silicon substrate, the Karger reference is clearly within the definition of a monolithic chip from the materials listed on page 2 lines 1-4 of the reference. Additionally the attached dictionary definitions of monolith and monolithic clearly show that the term monolithic can be applied to blocks of materials other than monocrystalline silicon substrates.

Applicant is required to cancel the new matter in the reply to this Office Action.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karger (WO 97/04297) in view of Miura or Fite and applicants' admission of the prior art as described on page 8, line 24 to page 10 line 15 of the instant specification. In the published application Karger teaches a microscale fluid handling system (10) including a substrate (11) with one or more channels (12) integrally formed in it. The channels terminate in one or more exit ports (16) which transfer a microscale quantity of a fluid sample traveling in the channels from the substrate to an external analytical and or collection system (23). The exit port or ports may be configured, for example, as an electrospray interface for transfer of a fluid sample to a mass spectrometer. The

channels extend to one or more planes in the substrate, and the substrate has multiple channels within a single plane. The substrate has multiple planes and is an optical grade material such as silica. One or more of the exit ports can lie in a plane different from a plane through one or more of the channels. The device permits efficient transfer of nanolitre quantities or other small quantities of fluid sample from spatially concentrated environment of microscale device, such as microfabricated chip, to off chip analytical or collection devices without increase in sample volume. Page 3 line 21 to page 4 line 15 teaches that samples can be introduced into a channel on the microscale device by a variety of methods, such as pressure, electrokinetic injection, or other technique. Migration of the sample within a channel may be produced by an electrical current and/or pressure drop applied to cause the sample components to migrate along the channel. The channels may function only for fluid transfer to a mass spectrometer or a collection device, or the channels can serve as environments for various types of sample manipulations such as capillary electrophoresis (CE) or polymerase chain reaction (PCR), or for carrying out any type of sample chemistry. The channels may be filled with membrane or packing material to effectuate preconcentration or enrichment of samples or for other treatment steps. Packing material may be bound to the walls of the channels or may include other components, such as magnetic particles, so that when a magnetic field is applied, the magnetic particles retain the packing material in place. A micromachined filter or other stationary structure may also be employed to hold packing material in place. Alternatively, stationary structures can be micromachined, cast or otherwise formed in the surface of a channel to provide a high surface area which can substitute for packing material. Another method of applying samples is to attach a miniaturized multiple-sample holder as a hybrid micromachined system to the entrance ports of the channels. Page 7 line 8-19 teach that buffer reservoirs, reaction chambers, sample reservoirs, and detection cells may also be fabricated along with each individual channel. More complex structures can be created by stacking or otherwise assembling two or more microfabricated devices. In addition, individual instrument blocks (devices) such as sample reservoirs, pretreatment or separation channels, and exit ports can be micromachined separately and combined into one complete system in much the same way as hybrid integrated circuits in electronics are formed. In figure 1a, element 20 shows a recess around the exit port while figures 2b-2d show other configurations for the exit ports. The recess is used to isolate the exit ports and reduce cross-contamination

between the channels. Figure 1c shows a design in which two parts are connected together and the electrodes are prior to the channels in the substrate. In this embodiment the inlet orifice and the ejection surface are located on opposed planar surfaces of the microchip body (11). Figure 3 shows a radial design. Page 14 lines 15-16 teach that the exit ports may be formed with electrodes to allow active control of their potential. Figures 2(b) and 2(c) show the formation of an ESI tip as the exit port. Karger fails to teach that the recessed portion completely surrounds the exit ports or that the substrate is a monolithic substrate.

In the patent Miura teaches an ink jet printer and method for preparation of ink-jet recording nozzles. The claimed process includes the following steps: (1) forming a rough surface on one side of a photosensitive glass which was patternwise exposed and crystallized, (2) forming on the above rough surface a resist pattern, and (3) etching through the above photosensitive glass to form nozzles. The rear nozzle member (7) formed through the process has a forwardly projecting nozzle (8, the nozzle has a recessed area around the nozzle) and a rear channel (9) extending from the liquid chamber (5) through the projecting nozzle in axial alignment with the front channel (2,3) to form a meniscus at the front end. An electric field gradient is established between the front channel and the meniscus using electrode means (6a) to cause the latter to extend toward the front channel and expelled through the front channel. A portion of the front nozzle member is rendered liquid-repellant (figures 11A-11C,12A-12B) to prevent the field distribution from being seriously disturbed by an ink layer formed on it by stray liquid particles. Various preferred forms of the rear nozzle plate are shown in figures 4A to 4F. The variations shown at figures 4A to 4D are advantageous to further increase meniscus stability and improve meniscus response characteristic. In figure 4E, the rear nozzle (8) is formed with an annular groove (80) to entrap liquid which might spill over the edge of the nozzle if an excessive amount of force is externally applied to the print head. This structure is equivalent to that shown in the figures shown in the instant application. The annular groove (81) may be provided around the nozzle (8) as shown in figure 4F. The nozzle dimensions are taught in column 5 line 67 to column 6 line 10 and would produce a nozzle within the required cross sectional area.

In the patent Fite teaches method and apparatus for mass spectrometry analysis of liquids which uses an electrospray technique to form the molecular ions. Figures 5A to 5E teach several configurations for the ejection nozzle or exit port of the capillary used to produce the

electrospray. Relative to the shape of the exit nozzle the discussions of the embodiments 5C and 5D are particularly relevant. From this it is clear to see that the nozzle of figure 5C allows the electrospray to be formed using lower voltages than are required by the shape of figure 5D by producing an annular bevel or recess surrounding the exit opening of the capillary.

In the above cited section of the specification, as originally filed, applicant is describing prior attempts to fabricate electrospray devices on a planar glass microchip. Of particular relevance is the device described in the Xue article. Which has an authorship that is identical to the Karger application and describes a device which is substantially similar to that of the Karger application. Additionally page 10, lines 9-11 characterizes the microchip of the prior art devices as "a monolithic chip". Thus the admitted prior art characterizes the Karger substrate as a monolithic substrate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to extend the recess taught by Karger so that it surrounds the exit port as taught by Fite or Miura because as taught by Fite and Miura it would reduce the voltage needed to produce the electrospray and as taught by Miura an annular groove would entrap any spilled liquid from the nozzle.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR

3.73(b).

5. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-14 of U.S. Patent No. 6,245,227. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim totally encompasses the patented claims.

6. Applicant's arguments filed December 2, 2002 have been fully considered but they are not persuasive. Relative to the argument about monolithic applicant is directed to the attached definitions for monolith and monolithic which show that monolith refers to a single block of material. Thus a monolithic substrate is simply a single block of material from which the component is made. This is consistent with the terminology used in the original specification and the correction does more than simply change a typographical error. Additionally applicant is trying to change wording in the specification that was used in the basis of the rejection. In the Karger reference both the substrate with grooves for the channels and the coverplate are monolithic substrates. Additionally Karger does teach a recessed region around the nozzle in figure 1a. Additionally with the above definition of monolithic figure 1c of Karger also appears to show a monolithic substrate for the nozzle portion of the device.

Relative to the double patenting rejection, applicant is invited to compare claim 13 of the patent with claim 10 of the instant application. In doing so it will be clear that all of the currently claimed features of instant claim 10 are found in the patented claim except the recitation of the substrate being a monolithic substrate. As outlined above the term monolithic refers to a single block of material which is clearly the scope of claim 13. Thus the patented invention and the instant claims are so close that the obviousness-type double patenting rejection is appropriate. Since the rejection is appropriate for the instant claims, suspension of its consideration is not appropriate. Thus it is not clear if applicant is requesting prosecution in the instant application to be suspended until the interference and/or lawsuit issues have been answered or if applicant is indicating that the instant application should be included in any interference involving the '227 patent.

Relative to the rejection based on the Karger reference, the change was necessitated by the amendment and the following comments are added by way of explanation of the rejection. In Karger the indentations or recesses (20) are there for the purpose of isolating adjacent nozzles

(exit ports) and avoiding or minimizing cross contamination between the channels. Fite, which discusses an electrospray nozzle and how the shape of the nozzle affects the electrospray. Relative to the shape of the recess taught by Karger, it is clear from the teachings of Fite relative to the shapes of the nozzles, that sharp edges result in high electric fields in the vicinity of the sharp edge with lower voltages than when there are no sharp edges on the nozzle. 5B and 5C show nozzles in which a cylindrical geometry is maintained and show how the shape of the nozzle can affect the size of droplets that are electrosprayed. One of skill in the art would have recognized that a nozzle structure in which the recess does not surround the nozzle may be easier to manufacture in the same way that figure 5D of Fite teaches, but it would result in the need to apply higher voltages to produce the electrospray. It would also be expected that a recess surrounding the orifice would reduce cross contamination by reducing the surfaces adjacent to the nozzle that lead to that problem. In the same sense Miura shows that the annular groove entraps liquid which one of skill in the art would have readily recognized as a source of cross contamination and would have incorporated it to improve the stated purpose of the recess or indentation taught by Karger. Relative to the Miura reference it is noted that formation of the droplets in both Karger and Miura is through a process that is substantially similar involving the use of an electric potential. Thus the teachings of Miura are relevant to the Karger device especially with respect to the reasons for the recesses between the plurality of nozzles in Karger. The purpose of the annular groove in Miura (entrapping liquid spilled from the nozzle) is similar to the purpose taught for the recesses of Karger (preventing contamination between nozzles by fluid which does not get sprayed). Thus one of skill in the art would have recognized that the groove of Miura prevents the excess fluid from affecting subsequent releases by trapping the fluid and would have incorporated the groove into the Karger device for that purpose.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



January 22, 2003

ARLEN SODERQUIST
PRIMARY EXAMINER

mon·o·lith (mon'ō lith), *n.* 1. a single block or piece of stone of considerable size, esp. when used in architecture or sculpture. 2. an obelisk, column, statue, etc., formed of a single block of stone. 3. something resembling a huge block of stone, esp. in having a uniform, massive, or intractable quality or character: *There's a crack in the Communist monolith, as shown in the charges made by China against Russia.* [*< LL monolith(us) < Gk monolíthos* made of one stone. See MONO-, -LITH]

—**mon·o·lith·ism**, *n.*

mon·o·lith·ic (mon'ō lith'ik), *adj.* 1. of or pertaining to a monolith. 2. made of only one stone: *a monolithic column.* 3. constructed of monoliths or huge blocks of stone: *the monolithic monuments of the New Stone Age.* 4. characterized by massiveness, total uniformity, and intractability: *a monolithic society; a monolithic state.* [*MONOLITH + -IC*] —**mon·o·lith·i·cal·ly**, *adv.*

